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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/805,122

03/20/2004

Andreas M. Papas

YH-AquaE

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06/24/2008

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EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

06/24/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/805,122	<b>Applicant(s)</b> PAPAS ET AL.	
	<b>Examiner</b> Eric E. Silverman, PhD	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-15, 22 and 23 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants' response, filed 4/12/2008, has been received. Claims 1 – 23 are pending, claims 16 – 21 being withdrawn from consideration. Claims 1 – 15, 22 and 23 are considered on the merits in this action.

#### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6, 8, 10, 11, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,824,638 to Burnside et al for reasons of record and those discussed below in the Response to Arguments section.

Claims 1, 2, 5, 6, 8, 10, 11, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,824,638 to Burnside et al for reasons of record and those discussed below in the Response to Arguments section.

Claims 1, 2, 5, 6, 7, 8, 10, 11, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/29300 (the '300 reference) for reasons of record and those discussed below in the Response to Arguments section.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 4, 9 and 13 – 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,824,638 to Burnsides et al. in view of US 5,883,103 to Burnsides et al., WO 99/29300, and Roy et al. in FEBS Lett. 2002 October 23; 530 (1-3):17-23 for reasons of record and those discussed below in the Response to Arguments section.

### ***Response to Arguments***

Applicants' arguments have been fully considered, but are not persuasive. Applicants argue that the amendment requiring that the solubilizing composition consist essentially of a mixture of vitamin E TPGS and linoleic acid overcomes the art of record. Applicants aver that the "consisting essentially of" language forecloses the inclusion of detergents or emulsifiers in the composition, except to the extent that the recited Vitamin E TPGS and linoleic acid are detergents or emulsifiers, and that the prior art does not contemplate the absence of detergents or emulsifiers. The transitional phrase "consisting essentially of" excludes any additional component, element or step that would fundamentally alter the novel characteristics of the invention. The instant specification describes the novel characteristics of the claimed invention. One such characteristic is that the invention overcomes various perceived drawbacks in the prior art, namely the low amount of Vitamin E that can be incorporated in an emulsion, and the lack of stability of such emulsions in that oil and water emulsions may phase-separate into separate oil and water phases. The other characteristic of the invention that are described as being novel are the high concentration of vitamin E that can be incorporated into the instant composition, so that an effective dose can be delivered in a

relatively low volume. It is noted that the disclosure does not state that a novel or characteristic of the invention is the absence of surfactants, detergents, or emulsifiers.

The question, therefore, is whether the prior art's inclusion of a detergent or surfactant would fundamentally alter these novel characteristics. It is well established that a surfactant or detergent has the effect of stabilizing an emulsion (see US 4,289,638). It is further understood that the use of surfactant or detergent increases the solubility (and thus final concentration) of a hydrophobic material in an aqueous environment. As such, it cannot be said that the inclusion of a surfactant, detergent or emulsifier detracts from or otherwise changes the novel characteristics of the invention. Therefore, the instant consisting essentially of language does not preclude their presence in the composition.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

Eric E. Silverman, PhD  
Art Unit 1618